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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,666	09/28/2001	Suzanne De La Monte	0609.4370003/RWE/FRC	3650

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WASHINGTON, DC 20005

EXAMINER

MCGARRY, SEAN

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 08/08/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicati n N .

09/964,666

Applicant(s)

DE LA MONTE ET AL.

Examiner

Sean R McGarry

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-- The MAILING DATE of this communication appears n the cover sheet with the c rresp ndence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disp sition of Claims**

- 4) ☒ Claim(s) 17-32 and 34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17,18,20-30,32 and 34 is/are rejected.
- 7) ☒ Claim(s) 19 and 31 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Pri rity under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *sequence alignment*.

#### **DETAILED ACTION**

Claim 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 depends from claims 32. Claim 32 is drawn to a composition. Claim 34 recites "The method of claim 32" which renders the claim indefinite since claim 32 is not a method.

Claims 17, 18, 20-30, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over de la Monte et al [WO 94/23756].

The instant invention is drawn to various antisense based compounds targeted to an mRNA that corresponds to nucleotides 150-1139 of SEQ ID NO: 1. The compounds are antisense oligonucleotides, ribozymes, triplex forming oligonucleotides and external guide sequences.

The de la Monte reference is drawn to the same target nucleic acid as the instant invention. The disclosure of de la Monte et al teaches making the same molecules as the instant invention but do not limit the target range to nucleotides 150-1139 of instant SEQ ID NO: 1. It is noted that the work of de la Monte et al is that of the instant inventors where it has been asserted in the instant specification that there were sequencing errors in WO 94/23756 where the instant sequence SEQ ID NO: 1 corrects those sequencing errors. However, it was clearly taught in applicants earlier document

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[Wo 94/23756] to make the same molecules now claimed across the entire mRNA of the "incorrect sequence" reported in the WO patent. However it is noted that a comparison (see attached sequence alignment of the instant SEQ ID NO: 1 and its corresponding sequence in WO 94/23756) of the sequence in WO 94/23756 clearly shows that there is sufficient similarity in the sequences that, by following the teachings of WO 94/23756, one would clearly have made antisense compounds as instantly claimed with the region instantly recited. Further it is noted that WO 94/23756 indicates at page 56 and 85 that a deposit of the AD10-7-DH1 was made to the ATCC under accession number 69262 which is the source of the errored sequence in WO 94/23756 and the "corrected" sequence of the instant application (see page 5 of the instant specification). Since the teachings (see pages 46-56, and claims 73-88, for example) of de la Monte et al parallel those of the instant specification in the design and production of the claimed antisense oligonucleotides, ribozymes, triplex forming oligonucleotides, and external guide sequences and since the sequence reported as "corrected" in the instant specification is so similar to that disclosed as errored in WO 94/ 23756 and further where the source of the correct sequence was available at the time of invention, one in the art would clearly have made antisense oligonucleotides, ribozymes, triplex forming oligonucleotides, and external guide sequences within the region instantly recited. The region instantly recited deletes the first 149 nucleotides of the target nucleic acid and has been eliminated as a target solely because it was not incorrectly sequenced (see page 25 of the instant specification, for example). The teachings of de la Monde et al clearly teach making the compounds over the entire target sequence and

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clearly some of these would fall within the range instantly recited (see pages 46-56 and claims 73-88, for example).

The invention as a whole would therefore have been *prima facie* obvious to one in the art at the time the invention was made.

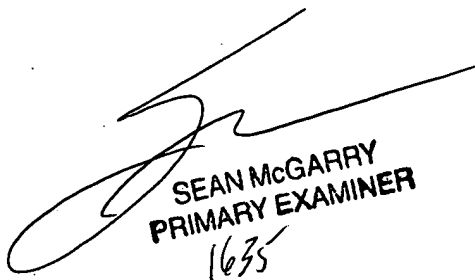
Claims 19 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (703)305-7028. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SRM  
August 6, 2003

  
SEAN McGARRY  
PRIMARY EXAMINER  
1635